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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,172	07/25/2001	Oren Globerman	110/02239	7714

7590 12/01/2004

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,172

Applicant(s)

GLOBERMAN ET AL.

Examiner

Paul B. Prebilic

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-149 is/are pending in the application.
- 4a) Of the above claim(s) 126-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 27, 28, 30, 31, 34-49, 51-68, 70, 78-81, 84-86, 89-119, 121-125, 148 and 149 is/are rejected.
- 7) ☒ Claim(s) 25, 26, 29, 32, 33, 50, 69, 71-77, 82, 83, 87, 88 and 120 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date various.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Claims 126-147 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 126-147 are directed to a method of inserting the device that is independent and distinct from the originally filed and previously prosecuted invention of a spacer. For this reason, the claims are withdrawn from consideration; see MPEP 819 and 821.03, which are incorporated herein by reference.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 126-147 were withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's arguments traversing the withdrawing of claims 126-147 in the reply filed on August 30, 2004 is acknowledged. The traversal is on the ground(s) that there is no additional burden to search the method claims. This is not found persuasive because searching the method claims may require the additional subclass searches of class 128/subclass 898, class 606/subclass 99 and class 623/subclass 908.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 113-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although support for axial dense regions can be found in the Figures 6T to 6V, the claimed ranges "on at least 40% of said body" and "at least 50% of the surface area" lack original support. For this reason, the Examiner asserts that these ranges constitute new matter with respect to the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 107-109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 107-109, the claim language is unclear because the tips as claimed should always be 100% of the contact surface as claimed because the tips are all that would contact a target vertebra. Rather, if applicant claimed that the spacer geometry had an outer surface such that the contact surface was a percentage of the outer surface, this would be clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-16, 19-24, 27, 28, 30, 31, 34, 35, 41-44, 46, 48, 51-62, 66, 68, 70, 78, 80, 81, 84, 86, 90-95, 103-112, and 121-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Pisharodi (US 5,693,100). Pisharodi anticipates the claim language where the tube as claimed is shown in Figure 7 of Pisharodi (see also column 7, lines 27-37), the slits as claimed are between sections (34), the axial displaced extensions are the axial aligned legs of subunits (34,36), and the locking element is the screw (42) with locknut (40); see the figures, column 4, line 58 to column 5, line 46.

Regarding claim 9, the slits between the legs are perpendicular or not parallel to the longitudinal axis.

Regarding claim 11, slits along the axis are of a different length than the slit between the legs.

Regarding claim 30, Pisharodi has two segments along the longitudinal axis.

Regarding claims 56, 59, 64, and 113, the cross-section claimed can be taken at an angle across any part of the device such that the claim language is fully met to the extent it can be given patentable weight.

Regarding claim 81, see Figure 6 or 7 where the bottom subunits (36) are connected at their tops.

Regarding claims 107 to 109, the tips are the only surfaces that would contact the vertebrae so they cover 100% of the contact surface.

Regarding claim 113 as amended, there are a total of 16 axially displaced extensions extending from the Pisharodi's Figure 7 body when it is expanded.

Claims 1, 125, 148, and 149 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer (US 3,846,846) where the extensions as claimed are the leading ends 9a of Fischer of the three axially aligned expansion elements of Figures 1 and 2; see also column 3, line 40 to column 4, line 54.

With regard to claims 1 and 148, the locking element as claimed is the made up of the nut (6), rod (7), and/or expander portion (8) of Fischer.

With regard to claim 125 and 149, since the Fischer device can be made of titanium (an extremely hard metal) and since the language "spinal forces applied in a direction radial to the spacer" is construed as quite broad, the Examiner asserts that the claim language is fully met by Fischer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 36-40, 45, 47, 49, 63-65, 67, 79, 85, 89, 96-102, 104-105, 113-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) alone.

Pisharodi meets the claim language but lacks curved slits (claim 5), a varied profile (claims 36-40), unevenly distributed extensions (claims 45, 47, 49), elliptical cross-sectioned tube (claim 63), rectangular trans-axial cross-section (claim 64), bent cross-sectioned tube (claim 65, 67), a twisted joint (claim 79), annealing (claim 85, 89),

shape-memory materials (claims 96, 97), or axial deformed at certain loads (claims 98-102). However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to vary the structure of Pisharodi because Applicants have not disclosed that varied structures provide some advantage, are used for a particular purpose, or solve stated problems. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well only slight variations in shape of size are required or deformation could be made at loads over 20 Kg (it is noted that the claims do not preclude deformation at lower loads than those claimed in claims 98-102). Therefore, it would have been an obvious matter of design choice to modify Pisharodi to obtain the invention as specified in the claims.

Claims 17, 18, and 119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Pisharodi (US 5,123,926).

Regarding claims 17, 18 and 119, Pisharodi discloses an expandable spacer but lacks the teaching of spurs on the spacer as claim. Pisharodi teaches of an artificial spine prosthesis with spurs (Fig. 3, Ref. Num. 8) to hold the prosthesis within the intervertebral disk space. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Pisharodi to have spurs on the outside of the spacer to better hold it in place.

Regarding claims 104-105 and 113-115, since the diameter of expansion can be incrementally varied, it follows that small fractions over the unexpanded diameter are

possible with Pisharodi's device such that the claimed diameter is clearly obvious over Pisharodi alone.

Claims 116-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (US 5,693,100) in view of Stubstad et al (US 3,867,728). Pisharodi meets the claim language as explained above, but fails to teach a coating of bioactive material as claimed. However, Stubstad teaches that it was known to use bioactive coatings to improve or prevent ingrowth; see column 11, lines 39-65. Therefore, it is the Examiner's position that it would have been obvious to put a bioactive coating on Pisharodi's device for the same reasons that Stubstad does the same.

Response to Arguments

Applicant's arguments with respect to have been considered but were not considered persuasive.

In response to the Applicants' assertion that original support for claims 113 to 115 can be found on page 16 of the specification is considered unpersuasive because the language and scope of that original disclosure is clearly different from what is now claimed. In particular, the original language said that the extension are merely "dense" not "axially dense" as now claimed and that the extension cover 50% of the body not that the extensions are dense on 50% of the body. For these reason, the Examiner maintains that the claim language of claims 113 to 115 lacks original support.

The argument that Pisharodi lacks at least two axially displaced extensions is not considered persuasive because the axially spaced legs (34) or (36) meet this claim

language fully. These legs are considered axially displaced from one another to the extent that this language can be given patentable weight. Note even that there is a gap between the outer ends of the legs when in the expanded configuration; see Figure 6 at reference number (50).

Furthermore, it appears that the Applicants have interpreted the rejection as only relying on the embodiment of Figure 6 and not Figure 7. Clearly, Figure 7 has 8 sides and 16 legs that constitute 16 extensions. The slits run along each leg and stop at the radial slit separating it from the next axially aligned leg.

Allowable Subject Matter

Claims 25, 26, 29, 32, 33, 50, 69, 71-77, 82, 83, 87, 88, and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 120, the Examiner is interpreting the claim language as comparing one extension to another extension of the claimed elongate body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
Art Unit 3738